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FEDERAL REGISTER

[FDA 225-84-8400]

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September 28, 1984

Memorandum of Understanding With the National Institute of Environmental Health Sciences' National Toxicology Program
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has executed a memorandum or understanding (MOU) with the **National Toxicology Program** (NTP) to formalize an agreement by which the parties will cooperate and share information to assure the quality and integrity of safety data. The agreement also promotes mutual cooperation towards ensuring that laboratories engaged in nonclinical testing are in compliance with good laboratory practice regulations.

DATE: The agreement became effective August 1, 1984.

FOR FURTHER INFORMATION CONTACT: Paul D. Lepore, Office of Regulatory Affairs (HFC-30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2390.

TEXT: SUPPLEMENTARY INFORMATION: In accordance with § 20.108(c) (21 CFR 20.108(c)) which states that all agreements and memoranda of understanding between FDA and others shall be published in the Federal Register, the agency is publishing the following memorandum of understanding:

Memorandum of Understanding Between the National Toxicology Program -- National Institute of Environmental Health Sciences and the Food and Drug Administration

I. Purpose

The National Toxicology Program (NTP) and the Food and Drug Administration (FDA) have a common objective of promoting the quality and integrity of safety evaluation data resulting from nonclinical laboratory studies. These data are ultimately used to support the approval of applications for research and marketing permits for products regulated by FDA or for health hazard assessment in the public sector. NTP and FDA have established an informal liaison which allows the exchange of information resulting from audits of toxicology laboratories. Both parties recognize the need to further this endeavor. This agreement will identify specific responsibilities of each party to foster communication and to promote mutual cooperation towards ensuring that nonclinical studies are performed in accordance with good laboratory practices.

II. Background

FDA became concerned with the quality of toxicology testing as a result of laboratory inspections that were conducted in 1975. Based on these findings, Congress provided resources to establish a program that would assure that safety studies are conducted using scientifically sound protocols and in a manner that does not adversely affect the validity of a study. FDA subsequently promulgated good laboratory practice regulations (GLP's) (21 CFR Part 58) that

prescribe good laboratory practice for conducting nonclinical laboratory studies and instituted a laboratory inspection program. The inspection program provides for the biennial assessment of current laboratory operations, as well as audits of final reports of nonclinical laboratory studies which have been submitted to FDA.

NTP, as a sponsor of contract research, adopted a policy that requires that new or existing NTP testing contracts include compliance with the FDA GLP's. NTP monitors their contractors by performing site visits to inspect the laboratory's operations and to review the records and reports associated with a nonclinical study.

III. Substance of Agreement

A. *FDA's Responsibilities:* 1. FDA will provide NTP with a list of NTP contract laboratories that FDA intends to inspect during a given fiscal quarter.

2. FDA will provide to NTP copies of GLP inspection reports and agency reviews of laboratories performing studies under NTP contracts.

3. FDA will immediately advise NTP of any serious violative findings resulting from investigations of laboratories that perform contract studies for NTP, and will provide copies of inspection reports and reviews including correspondence associated with any regulatory action as they become available.

4. FDA will provide to NTP on a quarterly basis a listing of laboratories engaged in toxicology testing that have been inspected by FDA.

5. FDA will maintain the confidentiality of any confidential information provided by NTP, and will refer to NTP any requests for disclosure of information that may be confidential.

B. *NTP's Responsibilities:* 1. NTP will advise FDA of planned audits of any contract laboratory that FDA has previously inspected for compliance with the GLP's.

2. NTP will make available to FDA copies of the GLP audit and GLP site visit reports resulting from an NTP site visit.

3. NTP will immediately advise FDA of any serious violative findings resulting from investigations at the contract laboratories.

4. NTP will provide to FDA a copy of their annual inventory of laboratories that are performing contract studies for NTP.

5. NTP will maintain the confidentiality of any confidential information provided by FDA and will refer to FDA any requests for disclosure of information that may be confidential.

IV. Participating Agencies

A. National Toxicology Program, National Institute of Environmental Health Sciences, P.O. Box 12233, Research Triangle Park, NC 27709.

B. Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

V. Liaison Officers

A. National Toxicology Program, Director, Toxicology Research and Testing Program, National Institute of Environmental Health Sciences (currently Dr. Ernest E. McConnell), P.O. Box 12233, Research Triangle Park, NC 27709, 919-541-3267.

B. Food and Drug Administration: Bioresearch Monitoring Staff, Office of Regulatory Affairs (currently Dr. Paul D. Lepore), 5600 Fishers Lane, Rockville, MD 20857, 301-443-2390.

VI. Duration of Agreement

This agreement will become effective upon acceptance by both parties and will continue indefinitely. It may be modified by mutual consent or may be terminated by either party upon a 30-day written notice to the other.

Approved and Accepted for the National Toxicology Program.

Ernest E. McConnell,

Acting Director, Toxicology Research and Testing Program.

Dated: August 1, 1984.

Approved and Accepted for the Food and Drug Administration.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

Dated: June 28, 1984.

Effective date. This agreement became effective August 1, 1984.

Dated: September 24, 1984.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

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